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FDA

Dockets Managements Branch - Docket #OOP-0169
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Dear Sirs:

I understand that you are involved with the decision whether to return Lotronex to the market. I ask you to give proper consideration to the profound, life-altering, suffering of those, such as myself, with severe IBS-D, and the lack of any effective alternative treatment. How often, in the course of our lives, do we have the opportunity to bring relief to hundreds-of-thousands of individuals who suffer from a debilitating, chronic, disease? We presently have that opportunity - we have to allow those suffering from IBS-D to have access to Lotronex. I urge you to do everything in your power to make this happen.

The initial decision to remove Lotronex from the market failed to recognize the severity with which IBS patients' lives can be impacted. Being house-bound, or struggling during every outing may not be fatal, but has a strong impact on quality-of-life. Drugs for other non-fatal conditions, such as sexual disfunction, are allowed to remain on the market in spite of known risks, due to quality-of-life benefits. The same should hold true for Lotronex.

I am a 43 year old male who has suffered from severe IBS-D since age 9. Although the severity of my illness has varied, it has had a profound impact on my life. There have been spans of many years where I've had to refrain from ALL activity other than that which was essential to survival. Simple activities, such as grocery shopping, or getting a hair-cut are traumatic. Even though I've lived close to work, commuting with IBS has been torture. I've tried all forms of treatment, including extensive psychotherapy, relaxation therapy and medication and have found, at best, modest improvement.

Lotronex has been the ONLY effective therapy for my IBS. Since my Lotronex supply has been depleted, I've encountered difficulties that threaten both my home life and my career. My frustration is compounded knowing the medication I need exists, and is only unavailable due to considerable mis-information regarding IBS.

You have, quite properly, made known the potential dangers of Lotronex, however, **I beg you to leave the risk/benefit assesment of Lotronex to well informed patients and their physicians.** Personally, given the choice of living 20 years as a free man or 40 years in prison, I would choose freedom. Please allow me to make that choice.

Thank you for your consideration,



Michael D. Kaiser

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